

**REMARKS**

Entry of the foregoing amendments and reconsideration of this application are respectfully requested in view of the following remarks. Claims 1, 3-14, 16-18, 20-22, and 27-35 are pending in the application, with claims 1, 12, 27, 28, and 32 being the independent claims. Claims 27-35 have been added. The Applicants respectfully submit that these amendments and new claims introduce no new matter. Based on the above Amendments and the following Remarks, the Applicants respectfully request that the Examiner reconsider and withdraw all outstanding rejections.

***Interview Summary***

On behalf of the Applicants, the undersigned wishes to express appreciation to Examiner Clow for the courtesies extended during the interview conducted on April 4, 2006. During the interview, Applicants' representatives discussed proposed amendments to the pending claims to address the rejections under §§ 101 and 112, 2<sup>nd</sup> paragraph, and discussed the applied references. The Examiner indicated that the proposed claim amendments overcame the rejections and that the amended claims distinguished over the cited art.

***Claim Objection***

The Examiner objected to claim 25 because of the awkward wording. Claim 25 has been amended. Accordingly, the objection to claim 25 has been rendered moot.

***The Claims Are Directed to Patentable Subject Matter and are Definite***

Claims 1-26 were rejected under 35 U.S.C. §§ 101 and 112, 1<sup>st</sup> paragraph as not being supported by a specific asserted utility or a well-established utility. Independent claims 15 and 24 have been canceled, rendering moot the rejections of those claims.

Independent claims 1 and 12 have been amended to be more specifically directed to the utility of testing or quality control for a biological diagnostic using data from an electrospray process. In particular, these claims have been amended to recite "if the test spectrum maps to the

n-dimensional space within an acceptable distance from the control centroid, submitting the test spectrum to the biological diagnostic.” In the interview, the Examiner indicated that such amendments would overcome the rejection under §§ 101 and 112, 1<sup>st</sup> paragraph.

New independent claim 27 is similarly directed to a testing or quality control for a biological diagnostic using data from an electrospray process that includes “if the spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, certifying the spectrum for analysis with the biological diagnostic.” The Examiner also indicated that this claim was directed to patentable subject matter. Similarly, new independent claims 28 and 29 are each directed to a quality control method for a bioassay and recite “determining a degree of error between the test centroid and the control centroid” and “comparing the at least one test centroid to the at least one control centroid to determine the displacement in the n-dimensional space of the at least one test centroid from the at least one control centroid; wherein the magnitude of the displacement is an indicator as to reliability of the bioassay process applied to the test sample,” respectively.

Claims 1-26 were also rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph as being indefinite. The Examiner specifically identified claims 1, 2, 5, 15, and 24 as requiring clarification. The Applicants note that the although the Office Action cites claim 5 as being rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, it appears that claim 6 rather than claim 5 was rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. The rejections based on claims 2, 15, and 24 have been rendered moot by the cancellation of those claims. Claim 1 has been amended to eliminate the phrase “determining whether the test spectrum obtained from said performing maps to the control model,” which was the basis for the Examiner’s rejection. Claim 6 has been amended to recited “the test diluent is a first diluent.”

Support for many of the claim terms is found in the present utility application in the Abstract, which refers to methods of quality assurance/quality control for bioassay processes “for obtaining spectral data...” The Abstract further describes methods that are based based on the locations in n-dimensional space of, and distances between, control model centroids and test sample centroids. Additional support in found in Para 0055 which explains that methods of the invention are “capable of distinguishing between different diluents or diluent concentrations” and in Para 0059 which explains that “diluents may be monitored for quality” such that substandard

diluents may be identified. Additional support support for claim elements is found in the specification at Para 0012 which describes the use of the present method as “improving the reliability of data obtained using the bioassay process.”

***The Claims are Allowable over the Prior Art***

Claims 1, 2, 5, 7, 10, 12, 13, 15, 17, 20, 21, and 23 were rejected under 35 USC § 102(a) as being anticipated by Petricoin et al. (Journal of the National Cancer Institute (2002) Vol. 94, No. 20, pages 1576-1578), as supported by Xiao et al. (Cancer Research (2001) Vol. 61, pages 6029-6033). Additionally, claims 1, 2, 3, 5, 7, 10, 12-17, 20, 21, 23-25 were rejected under 35 USC § 102(b) as being anticipated by Adam (PTO 1449 reference 19; Cancer Research (2002) Vol. 62, pages 3609-3614).

The Examiner indicated in the interview that the claims as proposed would overcome the rejections under 35 USC § 102. Accordingly, the Applicants respectfully submit that the currently amended independent claims and the new independent claims and those claims that depend therefrom are allowable.

**CONCLUSION**

All of the stated grounds of objection and rejection have been properly traversed or rendered moot. The Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding objections and rejections. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that further personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,  
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